

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Chambers of
Joseph A. Dickson
United States Magistrate Judge

Martin Luther King, Jr. Federal Bldg.
& U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102
(973-645-2580)

LETTER ORDER

July 14, 2020

To all counsel of record via ECF

**Re: In re: Allergan BIOCELL Textured Breast Implant Products Liability Litig.
Action No.: 19-MD-2921 (BRM) (JAD)**

Counsel:

This will address Plaintiffs' January 4, 2020 "Emergency Motion to Limit Communications With Class Members and their Physicians, Void Releases Signed by Class Members, and Issue Corrective Notice" (the "Emergency Motion"). (ECF No. 5). The undersigned conducted oral argument on Plaintiffs' Emergency Motion on April 29, 2020. For the reasons stated below, and for good cause shown, Plaintiffs' Emergency Motion is **GRANTED IN PART AND DENIED IN PART.**

I. RELEVANT PROCEDURAL HISTORY

This litigation, which concerns the alleged health risks associated with Defendants' (collectively "Allergan") now-recalled BIOCELL products (a line of textured breast implants and tissue expanders), began as a series of actions filed in judicial districts throughout the country. By Order dated December 18, 2019, the United States Judicial Panel on Multidistrict Litigation transferred several of those matters to the District of New Jersey, thereby creating Multi-District Litigation No. 2921. (ECF No. 1). The Panel has continued to transfer cases since

that time, and Plaintiffs have directly filed others, such that this multi-district litigation currently consists of more than 120 member cases.

On January 4, 2020, a group that identified themselves as the “Sloan Plaintiffs”¹ filed their Emergency Motion, seeking Court intervention in connection with Allergan’s alleged efforts to obtain warranty-related releases from putative class members who had their textured breast implants removed. (See generally Emergency Motion, ECF No. 5).² Plaintiffs argued that Allergan procured releases under two distinct warranty programs,³ but failed to provide patients or their surgeons with sufficient information regarding this litigation or the rights those patients would be giving up if they took advantage of the programs (e.g., that participation required a release of claims, including patients’ rights to participate in this litigation, the potential added benefits of pursuing litigation versus obtaining warranty coverage, etc.). (Pl. Br. at 3-7, ECF No. 5-1).

Plaintiffs sought multiple forms of relief, including an order: (1) prohibiting Allergan from communicating with putative class members and/or their surgeons “with respect to any request for a release that arises out of the subject matter of this litigation and/or any agreement that waives a class member’s right to recovery in this litigation”; (Pl. Br. at 1, ECF No. 5-1); (2)

¹ The “Sloan Plaintiffs” take their name from Angela Sloan, a named plaintiff in a case previously pending in the United States District Court for the Southern District of Iowa. (Emergency Motion at 1-2, ECF No. 5). The rest of the Sloan Plaintiffs are named plaintiffs in actions previously pending in the United States District Courts for the Eastern District of Michigan or the Eastern District of Pennsylvania. (*Id.*). It appears that the Sloan Plaintiffs chose their name based on the fact that, of three cases in question, Ms. Sloan filed her action first. Each of the Sloan Plaintiffs’ individual actions has been transferred to the District of New Jersey and incorporated into this multi-district litigation. (See Civil Action Nos. 19-22124, 20-223, and 20-1972).

² Though only the Sloan Plaintiffs initially filed the Emergency Motion, it appears that Plaintiffs, generally, have since joined in that application.

³ As discussed in Section II(a) below, the record now reflects that only one of those warranty programs, the ConfidencePlus Warranty, requires patients to provide Allergan with a release.

precluding Allergan from using any such releases going forward; (id. at 1-2); (3) requiring Allergan to provide Plaintiffs with the names and addresses of any putative class members who had initiated a warranty claim, provided a release, “and/or has been contacted concerning this action”; (id. at 2); and (4) permitting Plaintiffs’ counsel “to distribute a Court-approved Corrective Notice to all putative class members.” (Id.). By letter dated January 23, 2020, Allergan challenged several of the factual contentions Plaintiffs had made in their Emergency Motion.⁴

After carefully considering Plaintiffs’ application and Allergan’s initial, fact-based response, this Court determined that “a more fulsome record [was] necessary for the parties to properly brief and for the Court to resolve the Emergency Motion.” (Jan. 27, 2020 Order at 1, ECF No. 35). Therefore, by Letter Order dated January 27, 2020, this Court administratively terminated the Emergency Motion and directed the parties to engage in “limited, expedited discovery” intended to clarify the facts at issue. (See generally id.). By informal letter application dated January 29, 2020, Allergan sought reconsideration of the Court’s January 27, 2020 Letter Order, arguing that Plaintiffs’ Emergency Motion was legally doomed to fail and citing various practical concerns regarding the Court-Ordered discovery. (See generally Def. Jan 29, 2020 Letter, ECF No. 40). Allergan also sought a stay of the discovery requirements until after it had formally opposed the defunct Emergency Motion. (Id. at 1). By Order dated January 31, 2020, the Court stayed that discovery, and directed Plaintiffs to respond to Allergan’s informal request for reconsideration. (ECF No. 44). Plaintiffs opposed Allergan’s request by letter dated February 4, 2020. (Pl. Feb. 4, 2020 Letter, ECF No. 45).

⁴ Allergan submitted the January 23, 2020 letter directly to chambers via e-mail, rather than filing it on the docket for this matter. The letter, therefore, has no “ECF” citation.

On February 10, 2020, the Hon. Brian R. Martinotti, U.S.D.J., along with the undersigned, conducted a case management conference in this matter, at which time the Court addressed the posture of the Emergency Motion, among other things. On the same date, Judge Martinotti issued Case Management Order No. 3, in which His Honor required, in pertinent part, that Allergan file a formal response to Plaintiffs' Emergency Motion within eight days. (Case Management Order # 3 at 2, ECF No. 56). Allergan did so, filing its formal opposition on February 18, 2020. (ECF No. 57).

Though somewhat delayed by the intervening COVID-19 pandemic and practical constraints related thereto, the Court ultimately scheduled an oral argument on Plaintiffs' Emergency Motion for April 29, 2020. On the eve of that conference, Plaintiffs submitted a supplemental letter and exhibit containing new factual information. (Pl. Apr. 28, 2020 Letter).⁵ During oral argument, which the Court conducted by Zoom video conference, both parties represented that they believed the Court could resolve the Emergency Motion without the need for any additional fact discovery or supplementation. (Tr. of Apr. 28 Hr'g at 19:3-20:4; 27:8-28:14). The parties thereafter submitted additional letter briefing. (ECF Nos. 101, 103). Plaintiffs' application is now fully briefed and ripe for resolution.

II. DISCUSSION

a. Procedural Posture

As an initial matter, the Court must briefly address and clarify the unusual procedural posture of Plaintiffs' Emergency Motion. As noted in Section I above, the Court resolved that motion after reviewing Plaintiffs' application and Allergan's initial response, but before Allergan had occasion to submit a formal opposition. Allergan then requested that the Court reconsider

⁵ Plaintiffs e-mailed that letter directly to chambers, so it does not have an "ECF" citation.

that decision, before ultimately filing its opposition to Plaintiffs’ then-defunct Emergency Motion.

Considering that the Court initially ruled on the Emergency Motion before Allergan’s time to submit an opposition had run, it would be unfair to utilize the stringent standards applicable on motions for reconsideration. The Court will, therefore, **VACATE** its January 27, 2020 Order, reinstate Plaintiffs’ Emergency Motion, and resolve it based on the record that the parties have developed to date.

b. The Warranty Programs at Issue

i. ConfidencePlus Warranty

The first of Allergan’s two relevant warranty programs, the ConfidencePlus warranty, provides coverage for patients who have received certain medical diagnoses, including breast-implant-associated anaplastic large cell lymphoma (“BIA-ALCL”), capsular contracture, late seroma, and deflation. (Cert. of Timothy I. Duffy, Esq. (“Duffy Cert.”), Ex. D at 3, ECF No. 57-5). It offers various benefits depending on the medical condition at issue, including implant replacement and reimbursement of certain out-of-pocket expenses (including up to \$1,000 for diagnostic testing for BIA-ALCL when that condition is suspected). (*Id.* at 2-3). Allergan has conditioned its provision of benefits under the ConfidencePlus Warranty on certain prerequisites, including the patient’s execution of a general release. (*Id.* at 3). The specific language of the release provides that the patient “do[es] hereby release and forever discharge Allergan, Inc. and any related persons and entities . . . from all claims arising out of the use of [the textured breast implant products at issue in this case].” (Duffy Cert. Ex. E at 3, ECF No. 57-6).

To initiate a claim under the ConfidencePlus Warranty, a “surgeon must contact the Allergan Product Surveillance team prior to surgery . . . and provide the appropriate

documentation.” (Duffy Cert. Ex. D at 3, ECF No. 57-5). Post-surgery, the surgeon must return the explanted products and other documentation, including the patient’s general release, to complete the process. (Id.).

ii. BIOCELL Replacement Warranty

Following its voluntary recall of BIOCELL products from the global market, Allergan created the BIOCELL Replacement Warranty Program (“Replacement Warranty”). (Duffy Cert., Ex. B at 1, ECF No. 57-3; Ex. C at 1, ECF No. 57-4). Under the Replacement Warranty, if, after consultation with her surgeon, a patient chooses to remove her textured breast implants or tissue expanders, Allergan will provide that patient with new, smooth products at no cost. (Duffy Cert. Ex. B at 1-2, ECF No. 57-3). The Replacement Warranty does not, however, provide any reimbursement or other financial assistance for surgical costs. (Id. at 4). Moreover, unlike the ConfidencePlus Warranty, the Replacement Warranty provides coverage for asymptomatic patients. (Id. at 2-3). Based on the brochure for the Replacement Warranty and other relevant materials in the record, however, it does not appear that the Replacement Warranty is limited to asymptomatic patients. (See generally Duffy Cert., Exs. B, C).

As with the ConfidencePlus Warranty, a surgeon must initiate the claim process for the Replacement Warranty in advance of the explantation procedure. (Duffy Cert. Ex. B at 4, ECF No. 57-3; Ex. C at 2, ECF No. 57-4). Specifically, after the surgeon contacts Allergan:

Allergan Product Surveillance will request information about the devices being replaced and devices being requested. Allergan Product Surveillance will also provide a BIOCELL® Replacement Warranty program informed consent document for the patient to acknowledge that she has reviewed her options with [the surgeon], and has accepted the product conditions. Upon receipt of the signed consent document, replacement devices will be shipped to the specified address, or credited to the account if new products are used from your consignment.

(Duffy Cert. Ex B at 4, ECF No. 57-3). The record reflects that nothing in the informational materials Allergan provided to surgeons and/or their patients suggests that patients must sign releases to obtain coverage under the Replacement Warranty. (See generally Duffy Cert. Exs. B, ECF No. 57-3; Ex. C, ECF No. 57-4). Moreover, while the “informed consent” document that patients must sign in order to obtain coverage is labeled: “BIOCELL® Replacement Warranty Informed Consent and Release,” that document does not actually require patients to release any legal rights vis-à-vis the BIOCELL products. (Duffy Cert. Ex. F at 2-3, ECF No. 57-7). It simply authorizes the patient’s surgeon and Allergan to exchange the patient’s protected health information. (Id.).

c. The Parties’ Arguments

The parties appear to agree that, to the extent the Court takes action with regard to Allergan’s communications with putative class members, it would do so pursuant to Federal Rule of Civil Procedure 23(d). (Pl. Br. at 13-14, ECF No. 5-1; Def. Br. at 15, n. 11, ECF No. 57). The parties’ dispute focuses on three main points: (1) whether Plaintiffs have standing to seek relief with regard to patient releases; (2) whether the Court may lawfully restrict Allergan’s speech in accordance with the First Amendment; and (3) (assuming that the Court may restrict Allergan’s speech) whether the relief Plaintiffs have proposed would be appropriate under the circumstances of this case. The Court will address each in turn.

i. Plaintiffs Have Standing to Bring Their Emergency Motion

The Court must first determine whether any Plaintiff has standing to seek relief with regard to Allergan’s warranty-related interactions with class members (or putative class members). Allergan contends that they do not, arguing that “Plaintiffs proffer no evidence that even one of the more than 100 named Plaintiffs – or any putative class member – ever signed a

release of claims, let alone one “extracted” or “coerced” by Allergan.” (Def. Br. at 8, ECF No. 57). Citing the Supreme Court’s decision in Spokeo, Inc. v. Robins, -- U.S. --, 136 S. Ct. 1540 (2016), Allergan argues that the injuries Plaintiffs complain of are hypothetical and, therefore, not suitable for judicial consideration. (Id. at 7-9).

Plaintiffs, however, have proffered information that Amber Ferrell-Steele, a named plaintiff in this litigation, did, in fact, sign a release that Allergan sent to her surgeon. (Tr. of Apr. 29, 2020 Hr’g at 13:17-15:2). The record also reflects that Allergan sent the challenged release to a putative class member: Cinthia Koby Czerwinski (through her surgeon as an intermediary). (Decl. of Cinthia Koby Czerwinski (“Czerwinski Decl.”) ¶¶ 5-9, ECF No. 7). The Court finds that these examples create sufficient standing such that it may consider the merits of Plaintiffs’ Emergency Motion.

ii. Plaintiffs Have Established a Basis For Limiting Allergan’s Communications With Potential Class Members

A. Legal Standard

Federal Rule of Civil Procedure 23(d) governs the Court’s authority to manage class action litigation pending before it. It provides, in pertinent part, that a court “may issue orders that . . . determine the course of proceedings . . . impose conditions on the representative parties . . . or . . . deal with similar procedural matters.” Fed. R. Civ. P. 23(d). That supervisory authority extends to communications between parties and putative class members. In re Currency Conversion Fee Antitrust Litig., 361 F. Supp. 2d 237, 252 (S.D.N.Y. 2005). “Rule 23 specifically empowers district courts to issue orders to prevent abuse of the class action process. This power furthers the Federal Rules’ dual policy of protecting the interests of absent class members while fostering the fair and efficient resolution of numerous claims involving common issues.” In re Sch. Asbestos Litig., 842 F.2d 671, 680 (3d Cir. 1988). Considering the breadth

and import of Rule 23, the Supreme Court has observed: “[b]ecause of the potential for abuse, a district court has both the duty and the broad authority to exercise control over a class action and to enter appropriate orders governing the conduct of counsel and parties.” Gulf Oil Co. v. Bernard, 452 U.S. 89, 100, 101 S. Ct. 2193, 2200, 68 L.Ed.2d 693, 703 (1981). The Supreme Court cautioned, however, that “this discretion is not unlimited, and indeed is bonded by the relevant provisions of the Federal Rules.” Id.

One particularly sensitive subject area concerns requests to limit a party’s allegedly misleading or abusive communications with putative class members. On the one hand, “[m]isleading communications to class members concerning the litigation pose a serious threat to the fairness of the litigation process, the adequacy of representation and the administration of justice generally.” In re Sch. Asbestos Litig., 842 F.2d at 680 (citing Gulf Oil, 452 U.S. at 101 n. 12). On the other, “[o]rders regulating communications between litigants . . . pose a grave threat to first amendment freedom of speech. Accordingly, a district court’s discretion to issue such orders must be exercised within the bounds of the first amendment and the Federal Rules.” Id. (citing Gulf Oil, 452 U.S. at 101-02). In Gulf Oil, the Supreme Court created a standard to balance these concerns. To the extent a court is considering entering an order “limiting communications between parties and potential class members,” it must ensure that any such order is “based on a clear record and specific findings that reflect a weighing of the need for a limitation and the potential interference with the rights of the parties.” Gulf Oil, 452 U.S. at 100. “Only such a determination can ensure that the court is furthering, rather than hindering, the policies embodied in the Federal Rules of Civil Procedure, especially Rule 23.” Id. A court need not find that a challenged communication has caused actual harm, however, as Rule 23 also “authorizes the imposition of a restricting order to guard against the ‘likelihood’ of serious

abuses.”” In re Sch. Asbestos Litig., 842 F.2d at 683 (quoting Gulf Oil, 452 U.S. at 104) (emphasis in original).

B. Gulf Oil Analysis

While Plaintiffs originally challenged Allergan’s use of both the Replacement Warranty and ConfidencePlus Warranty, (see generally, Pl. Br., ECF No. 5-1), the parties have come to focus their arguments exclusively on the ConfidencePlus Warranty as the motion record has developed. As noted above, only the ConfidencePlus Warranty conditions benefits on a patient’s execution of a release. The Replacement Warranty does not, meaning that its continued use would have no impact on any putative class members’ rights in this litigation. If, for instance, an asymptomatic patient has her BIOCELL textured breast implants replaced under that program, and later develops BIA-ALCL, she may still sue Allergan. Allergan has explicitly acknowledged this. (Tr. of April 29, 2020 Hr’g at 5:14-7:3). Plaintiffs have not suggested how the Replacement Warranty is otherwise misleading or abusive. Therefore, even if Plaintiffs were still pursuing relief with regard to the Replacement Warranty, the Court finds that such relief would not be appropriate under Gulf Oil. The Court will therefore focus its analysis on Plaintiffs’ primary target: the release requirement in Allergan’s ConfidencePlus Warranty.

Plaintiffs challenge Allergan’s practice of procuring releases from putative class members in exchange for benefits under its ConfidencePlus Warranty program. Plaintiffs contend, for instance, that “[i]n connection with the release, [Allergan] has failed to advise class members of their rights, the existence of these lawsuits, or the fact that women are releasing their right to seek recovery from [Allergan] if they develop BIA-ALCL as a result of the Recalled BIOCELL Implants.” (Pl. Br., at 15-15, ECF No. 5-1). In support of their argument, Plaintiffs

have presented the accounts of Cinthia Koby Czerwinski and Amber Ferrell-Steele, a putative class member and named plaintiff, respectively.⁶

The first patient, putative class member Cinthia Koby Czerwinski, represents that she learned of the BIOCELL recall in September 2019 and had her BIOCELL breast implants removed the same month. (Czerwinski Decl. ¶¶ 5-6, ECF No. 7). Mr. Czerwinski states that her surgeon thereafter sent her a “Product Claim Form and ConfidencePlus® Warranty Release” document, along with instructions for her to complete and return that form within 24 hours in order to receive warranty benefits. (*Id.* ¶¶ 6-9, Ex. A). Ms. Czerwinski attached an unsigned copy of that form, which contains the release provision discussed in Section II(a)(i) above, as an exhibit to her Declaration. (*Id.* at Ex. A). Ms. Czerwinski represents that Allergan: (1) never informed her of the BIOCELL recall; (2) never communicated with her directly regarding the claim form; (3) never advised her of any pending class action litigation related to the BIOCELL recall; (4) never advised her that her recalled breast implants put her at an increased risk of developing BIA-ALCL; and (5) did not advise her (before she received the release document itself) that filing a claim under Allergan’s warranty program would require her to relinquish her legal rights regarding the BIOCELL implants. (*Id.* ¶¶ 4, 10-14).

⁶ Plaintiffs have also described the experiences of a third patient: Debbie Andrews. (*See generally* Decl. of Debbie Andrews ECF No. 8). Ms. Andrews had her breast implants removed after hearing of the BIOCELL recall, and contacted Allergan several times after learning, through social media, that “Allergan was providing financial compensation to women with recalled implants.” (*Id.* ¶¶ 4-6). Ms. Andrews contends that Allergan provided her with incomplete information during those communications, and ultimately advised that she must go through her surgeon to initiate a warranty claim. (*Id.* ¶¶ 7-13). She did so, and Allergan provided her surgeon with an application for coverage under the Replacement Warranty. (*Id.* ¶ 12, Ex. A). Allergan did not present her with an application concerning the ConfidencePlus Warranty, let alone the release related to that program. (*See generally id.*). The Court therefore finds that Ms. Andrews’ account is not probative of the release issue.

Allergan has not addressed the substance of Ms. Czerwinski's representations, arguing instead that: (1) she lacks standing because she declined to sign the release; and (2) Allergan could not have engaged in misleading or abusive communications with Ms. Czerwinski, because it solicited the release through her surgeon. (Def. Br. at 8-9, 17, ECF No. 57). Allergan's standing argument is misplaced. Ms. Czerwinski is not seeking relief here. She is a fact witness who has submitted a declaration describing her interactions with Allergan. Fact witnesses require personal knowledge, not legal standing. Nor is the Court swayed by Allergan's "straw man" argument. Allergan cannot inoculate its communications by transmitting them to patients through a third-party that Allergan itself requires as part of the warranty process. The communication in question here –the ConfidencePlus release – is Allergan's. Allergan controls every aspect of that document: its content, its timing, its applicability, and its conveyance. When it sends the release to patients through its chosen method of conveyance, it has communicated with those patients.

Plaintiffs also presented the case of Amber Ferrell-Steele, one of the Sloan Plaintiffs. Plaintiffs represent that Ms. Ferrell-Steele is an asymptomatic woman who had her breast implants removed based solely on her fear of developing BIA-ALCL. (Tr. of Apr. 28, 2020 Hr'g at 15:6-8). By letter dated April 28, 2020, Plaintiffs submitted a "Product Claim Form and ConfidencePlus® Premier Warranty Release" form, which Ms. Ferrell-Steele had executed. In response to Plaintiffs' arguments regarding Ms. Ferrell-Steele, Allergan's counsel represented that Ms. Ferrell-Steele's "physician reported to Allergan that her patient experienced a rupture and intended to have her implants removed because of the rupture." (Def. May 6, 2020 Letter at 1, ECF No. 101). Plaintiffs thereafter submitted a letter stating: "Plaintiff's medical records reflect that she chose to have the recalled implants removed based on [fear of BIA-ALCL]. It

was not until the surgery was performed that her physician discovered one of the implants had ruptured.” (Pl. May 6, 2020 Letter at 1, ECF No. 103). Of course, it is not possible for both of these explanations to be true. Perhaps Plaintiff Ferrell-Steele’s surgeon submitted a claim under the ConfidencePlus Warranty program after discovering the rupture. Alternatively, perhaps Allergan placed Ms. Ferrell-Steele into the claim process upon learning of the rupture. It does not impact the Court’s analysis at this point. What matters is that Ms. Ferrell-Steele had her BIOCELL breast implants removed, post-recall, and Allergan conveyed the ConfidencePlus release to Ms. Ferrell-Steele for her review and execution.

In addition to its arguments attacking the sufficiency of Plaintiffs’ proffers regarding Ms. Czerwinski and Ms. Ferrell-Steele, Allergan has also made global arguments in defense of its ConfidencePlus Warranty. Allergan essentially contends that Plaintiffs’ concerns about the warranty programs are factually baseless, because: (1) while the ConfidencePlus Warranty requires patients to sign a release, asymptomatic women are not eligible for coverage under that program; and (2) the release requirement is explicit in the relevant paperwork for the ConfidencePlus Warranty. (Def. Br. at 13-14, ECF No. 57; Tr. of Apr. 28, 2020 Hr’g at 9:21-10:14; 25:2-26:7). Thus, because asymptomatic women who choose to have their BIOCELL products removed due to a fear of developing BIA-ALCL would never have occasion to sign a release (i.e., because only the Replacement Warranty would apply to them), the ConfidencePlus Warranty’s release provision cannot possibly mislead or otherwise impact that group of plaintiffs. As for patients who decide to remove their breast implants after being diagnosed with a medical condition, Allergan contends that the ConfidencePlus Warranty’s release requirement is clear on its face, and thus creates no potential for confusion or abuse. In the context of this case, and based on the record developed to date, this Court disagrees on both points.

The Court will first address Allergan's contention that asymptomatic women, such as the Sloan Plaintiffs, are "not eligible" to submit a claim under the ConfidencePlus Warranty program and, as such, could never be put in a position to sign a release of their legal claims. (Tr. of April 29, 2020 Hr'g at 10:6-14; 22:13-23:9). That should be true, based on Allergan's representations regarding how the ConfidencePlus Warranty program works. (See Section II(b)(i), supra) (reflecting that a surgeon must contact Allergan before explantation to arrange for coverage under the ConfidencePlus Warranty). And yet, the record on this motion, developed prior to any discovery, reflects that it has happened to at least one named plaintiff and one putative class member.⁷ As discussed above, both Cinthia Koby Czerwinski and Ms. Amber Ferrell-Steele represent that they elected to have their breast implants removed after learning of the BIOCELL recall despite being asymptomatic, and Allergan, through the patients' surgeons, presented both with a ConfidencePlus release to sign post-surgery. (Czerwinski Decl. ¶¶ 5-9, ECF No. 7; Tr. of Apr. 28, 2020 Hr'g at 15:6-8; Pl. May 6, 2020 Letter at 1, ECF No. 103). The Court therefore finds that, to the extent the ConfidencePlus Warranty program's release requirement constitutes a misleading or abusive communication, it would present a risk to both asymptomatic women, as well as those with medical issues.

The Court next turns to the ConfidencePlus Warranty release itself, and examines its potential to mislead, coerce, or otherwise harm putative class members. Allergan urges the Court to consider the propriety of the release in a vacuum, focusing solely on the words contained therein. (See, e.g., Tr. of April 29, 2020 Hr'g at 25:2-17) (referring to the release

⁷ During oral argument, Plaintiffs' counsel represented that Plaintiffs are "aware of more than a dozen women who have signed [the ConfidencePlus] release". (Id. at 23:11-12). It is unclear, however, if those women (or their surgeons) commenced a claim under the ConfidencePlus Warranty in connection with a medical condition, or if the patients had their breast implants removed due solely to a fear of developing BIA-ALCL.

provision as “absolutely complete and comprehensive and appropriate”). But the pertinent consideration is not whether the release would be enforceable under principles of contract law. Rather, the Court must focus on the communication as a whole, including the circumstances of its conveyance, to properly evaluate its potential to mislead or coerce, as well as its potential impact on this litigation.

The Court begins with the fact that each of the women who receive the proposed release from Allergan will have had a surgical procedure to address BIOCELL breast implants that have been recalled due to their link to BIA-ALCL. Some, such as Cinthia Koby Czerwinski, will have removed their breast implants due to fear of developing the disease, while others may have actually been diagnosed with BIA-ALCL. All are likely under intense stress. Their surgeons, medical professionals to whom these women have previously entrusted their very lives, later provide the patients with the ConfidencePlus Warranty claim documentation at Allergan’s direction, with instructions to sign and return the release in order to obtain some remuneration from the company. (See Czerwinski Decl. ¶¶ 6-7, ECF No. 7) (noting that her surgeon advised that she “needed to return the form to [her] surgeon’s office within 24 hours in order to be eligible for the warranty benefits.”). The Court finds that the context, timing, and method of conveying the release all contribute to a serious risk of coercion and abuse.

The Court next considers the content of the release. As Allergan points out, the release appears to be, on its face, a typical, broad release of all present and future claims related to the BIOCELL products. (Duffy Cert. Ex. E at 3, ECF No. 57-6). The language it includes seems noncontroversial. It is the critical information that Allergan omits that makes it problematic. Allergan’s supposedly “complete and comprehensive” release language merely indicates that Allergan may compensate patients for “breast implant replacement surgery expenses of up to the

amount of \$7,500.00” in exchange for that all-encompassing release. (Duffy Cert. Ex. E at 3, ECF No. 57-6). The release makes no mention of: (1) the fact that the patient’s breast implants have been recalled due to their link to BIA-ALCL, a rare form of cancer; (2) the fact that the patient may develop BIA-ALCL at a later date, becoming burdened with the health effects and expenses associated with that condition; or (3) the fact that signing the release may extinguish the patient’s legal rights concerning any BIA-ALCL-related injuries. (Duffy Cert. Ex. E at 3, ECF No. 57-6). Equally problematic is the fact that Allergan makes no mention of the massive pieces of litigation, including this multi-district litigation, that it is actively litigating regarding the recalled BIOCELL products and their alleged link to BIA-ALCL, let alone that signing the release may preclude the patients from participating in those cases. (*Id.*). Nor does the release indicate that patients have an opportunity to discuss the release with an attorney. Indeed, the quick turnaround (i.e., Ms. Czerwinski was instructed to return her signed release within 24 hours) seems designed to forestall careful consideration.

Allergan has repeatedly argued that the ConfidencePlus Warranty has “been in place for more than 20 years,” (Tr. of April 29, 2020 Hr’g at 3:6-7; 4:16), as if the program’s longevity insulates it from scrutiny. Regardless of its history, Allergan is now using the ConfidencePlus Warranty to obtain releases from patients who are putative class members in a case pending before this Court. Those releases require patients to give up any potential recovery in this case, even if those patients have no idea that this case exists, or that it may ultimately provide them with a better result than that available under the ConfidencePlus Warranty. The Court finds that, in the context of this ongoing litigation, and in its current form, Allergan’s release impermissibly threatens to influence putative class members’ choice of remedies. *In re Sch. Asbestos Litig.*, 842 F.2d at 683.

Finally, the Court acknowledges that, in defense of its release, Allergan argues that the Court should preserve a patient's right to choose warranty coverage over litigation. This Court agrees. In the context of this litigation, however, patients presented with that release are not provided with critical information necessary to make a meaningful choice. Considering the foregoing in its entirety, the Court finds that, in its current form, Allergan's solicitation of releases from putative class members in exchange for coverage under the ConfidencePlus Warranty carries with it a sufficiently serious likelihood of abuse to justify a limited prior restraint on Allergan's First Amendment Rights.

iii. **Form of Relief**

Having found that the circumstances of this case justify a prior restraint on Allergan's First Amendment right to communicate with putative class members, the Court must attempt to fashion an appropriate remedy. In doing so, the Court is mindful that any such relief must be "carefully drawn" such that it "limits speech as little as possible, consistent with the rights of the parties under the circumstances." Gulf Oil Co., 452 U.S. at 102; 101 S. Ct. at 2201; 68 L. Ed.2d at 704.

As discussed above, Plaintiffs seek several forms of relief herein, including an order: (1) prohibiting Allergan from communicating with putative class members and/or their surgeons "with respect to any request for a release that arises out of the subject matter of this litigation and/or any agreement that waives a class member's right to recovery in this litigation"; (Pl. Br. at 1, ECF No. 5-1); (2) precluding Allergan from using any such releases going forward; (id. at 1-2); (3) requiring Allergan to provide Plaintiffs with the names and addresses of any putative class member who had initiated a warranty claim, provided a release "and/or has been contacted concerning this action"; (id. at 2); and (4) permitting Plaintiffs' counsel "to distribute a Court-

approved Corrective Notice to all putative class members.” (Id.). The Court finds that none of those remedies would be appropriate at this juncture.

The Court is not seeking to forever prohibit Allergan from obtaining releases from putative class members. Indeed, Allergan is correct that some women may choose to accept warranty coverage and avoid litigation altogether. The Court must permit them to do so. Instead, the Court’s objective is to even the informational playing field, so to speak, so that all patients have the information and time necessary to make an educated, meaningful choice about their legal rights. At a minimum, when providing the proposed release to patients, Allergan must explicitly advise them: (1) that the BIOCELL breast implant products have been recalled; (2) that litigation exists concerning issues related to that recall, and that the patient may be a putative class member in that litigation; (3) that by signing the release, the patient would be forfeiting any right to participate in that litigation or to share in any of the relief obtained therein; (4) the patient has at least a week to review the release and determine whether to sign it; and (5) the patient has the right to have an attorney review the release and advise the patient of her legal rights.

Finally, the Court declines, at this juncture, to invalidate the releases Allergan has obtained to date. Any determination regarding the legal impact of those releases should be made on a case-by-case basis at a later date. The Court finds, however, that the patients who signed those releases must be provided information about their opportunity to challenge them. In order to permit them to make a meaningful choice in this regard, Allergan must provide them with the same information, described above, that it must provide to potential releasors. In addition, Allergan must advise them that they may make an application to invalidate the release at a later date.

III. CONCLUSION

Based on the foregoing, **IT IS** on this 14th day of July, 2020,

ORDERED that the undersigned's January 27, 2020 Order, (ECF No. 35), is hereby **VACATED**; and it is further

ORDERED that Plaintiffs' Emergency Motion, (ECF No. 5), is hereby reinstated; and it is further

ORDERED that Plaintiffs' Emergency Motion is **GRANTED IN PART AND DENIED IN PART**; and it is further

ORDERED that the parties shall meet and confer regarding appropriate revisions to the ConfidencePlus Warranty release, as well as an appropriate notice to send to putative class members who have already signed a release. That release and supplemental notice must be consistent with the Court's directives provided herein. **On or before August 14, 2020**, the parties shall present those proposed documents to the Court for its review.

SO ORDERED

s/ Joseph A. Dickson
JOSEPH A. DICKSON, U.S.M.J.

cc: Honorable Brian R. Martinotti, U.S.D.J.